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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,953	02/05/2002	Robert A. Rabiner	20563/2112	6319
26161	7590	06/16/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MANTIS MERCADER, ELENI M	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,953

Applicant(s)

RABINER ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner respectfully disagrees with Applicant's arguments, which are narrower than what is currently claimed. The claims state nothing with respect to wavelength equations or longitudinal versus transverse waves. The claims refer to transverse ultrasonic vibration. Anti-nodes or loops inherently cause transverse vibration or cavitation and since these multiple loops are located across the length of the probe, vibration or cavitation occurs at these locations along the length of the probe. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Double Patenting rejections are maintained as the type of tissue being treated is merely intended use. For at least these reasons the rejections are maintained and made final. The 101 rejection is withdrawn as the amendment overcame this rejection. The non-challenged Official Notice regarding usage of imaging modalities is herein admitted.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-86 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 8-9, 11-12, and 15-18 of U.S. Patent No.

6,524,251. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the patented claims.

3. Claims 1-8, 11-13, 19-27, 30-32, 38-46, 49-51, 57-65, 68-70, and 76-86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending Application No. 09/975,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 09/975,725.

Furthermore, it would have been obvious to one skilled in the art at the time that the invention was made to have utilized the apparatus and procedure at any desired area of interest either for destruction and removal of the tissue of interest such as cancer cells or alternatively destruction and removal of an occlusion in a blood vessel.

4. Claims 1-86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 15-18 of copending Application No. 09/776,015. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 09/776,015.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-28 and 49-60 of copending Application No. 09/625,803. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 09/625,803.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-86 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16,18,20-27,29,31 and 32 of copending Application No. 09/917,471. Although the conflicting claims are not identical, they are not patentably distinct from each other because they represent obvious alternate variations and groupings of the presented claims in Application No. 09/917,471.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title; if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai et al.'144.

Sakurai et al.'144 teach all the elements of the current invention including a device for removing occlusions in blood vessels (col. 1, lines 12-53) comprising: an ultrasonic probe having a proximal end and a distal end (see in Figure 13, alternative ultrasonic probes 61 and 62, both having a proximal end and a distal end); a sound conductor with a proximal end and a distal end, said distal end being connected to the coupling assembly and said proximal end being connected to a transducer capable providing ultrasound energy (see Figure 13, element 63; and also see col. 12, lines 45-68 and col. 13, lines 1-6), to transmit ultrasound energy from said transducer to said probe, causing said probe to be oscillated in a substantially transverse mode to the probe longitudinal axis and wherein the probe is capable of supporting standing transverse sound waves to cause generation of ultrasonic cavitation energy in at least one location along the longitudinal axis of the ultrasonic probe (in Figure 13, see how the horn (element 63) transmits the vibrations to the ultrasonic probes (elements 61 or 62), through the attachment means (elements 73a and 73b); regarding the transverse oscillation of the probe see Figures 40 and 41 and indications of anti-node or loops wherein there is maximum oscillation along the length of the probes) and wherein the sound conductor and transducer (vibrating at an ultrasonic frequency) are in the device handle as illustrated by Figure 13.

Sakurai et al.'144 teach that the ultrasonic cavitation energy is preferentially enhanced at the distal portion of said probe (see for example Figures 41 and 42 indicating a loop at the distal end of the probe providing for maximum oscillation at the distal end also see col. 13, lines

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46-50; describing the vibration of the probe at the tip of the probe which is operating at maximum oscillation).

Sakurai et al.'144 teach an embodiment wherein the diameter of the probe is tapered allowing for a more vigorous vibration at its tip (see in Figure 13 probe 62 wherein its diameter is tapered allowing for a more vigorous vibration at its tip).

Sakurai et al.'144 teach the use of a sheath (see col. 19, lines 36-47).

Sakurai et al.'144 teach at least one aspiration channel (col. 12, lines 54-56; referring to suction path 68).

Sakurai et al.'144 teach the use of titanium as the material of choice for the probes (col. 14, lines 6-9).

Sakurai et al.'144 teach the sheath assembly further comprises at least one reflective element and an imaging assembly (in Figure 125, element 441 constitutes a reflective element and is part of the endoscope which is surrounded by the sheath in the embodiment of Figure 30). Alternative imaging assemblies would have been an obvious modification to one skilled in the art at the time that the invention was made, or otherwise stated it would constitute an alternative functional equivalent, substituting with alternative imaging modalities, resulting the same end-result which is imaging the area of treatment.

Sakurai et al.'144 do not teach use of the probe for destruction of tumor cells in the uterus. It would have been obvious to one skilled in the art at the time that the invention was made to have utilized the apparatus and procedure at any desired area of interest for destruction and removal of the tissue of interest. Therefore, it would have been obvious to one skilled in the

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art at the time that the invention was made to have emulsified and/or fragmented the tissue of interest such as destruction of cancer cells in the uterus.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eleni Mantis Mercader
Primary Examiner
Art Unit 3737

EMM